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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/632,054 | 07/31/2003 | Robert E. Richard | 02-465 | 9964 |

27774 7590 08/21/2009

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| EXAMINER | |
|---|---|
| HUGHES, ALICIA R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

| MAIL DATE | DELIVERY MODE |
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| 08/21/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Advisory Action Before the Filing of an Appeal Brief | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/632,054 | RICHARD ET AL. | |
| | Examiner | Art Unit | |
| | ALICIA R. HUGHES | 1614 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 07 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: *1,3-13,16-18 and 30*.
Claim(s) withdrawn from consideration: *15 and 19-29*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Raymond J Henley III/
Primary Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because:
With regard to the obviousness double patenting rejection over U.S. Patent No. 7,241,455 [the "Richard patent"], Applicant argues that unlike the Richard patent, the instant invention teaches the opposite of cross-linking to reduce molecular weight. This argument remains ubpersuasive, because both sets of claims substantially retain the same limitations, bringing the instant invention within the purview of the first invention.

With regard to the 103(3) rejection, the Applicants continue to argue that none of the references alone or in combination teach or suggest the current invention. Applicants have focused on a number of distinctions in individual references to support their claim that the instant invention is not prima facie obvious. The Examiner instead focuses on why the references may be read in tandem to reach a conclusion of obviousness by one of ordinary skill in the art.

Importantly, these 2.5 Mrads do read on the instant invention, which calls for a radiation dose that is at least 100,000 rads and claim 30, which has a range of 1 Mrad to 10 Mrads.
Further, Applicants' argue that there is no teaching or suggestion in Phan et al of polymers in which radiation is used to increase release of a therapeutic agent from a polymer is unfounded. Rather, as noted prior, it logically follows that the same therapeutic agent comprising the same polymeric release region is used in the same host, subject to a radiation dose that gives the same effect to the same patient population (Please see Col. 6, lines 29-33). And further as noted prior, by Applicants' own account, "when polymers are exposed to radiation, at least two reactions are believed to occur" and "[c]rosslinking generally results in …[and c]hain scission, on the other hand generally results in ...While polymers may display both types of reactions, one type of reaction will typically dominate. For increased release, it is preferred to use polymers in which chain scission reactions dominate." (Emphasis added).

Applicants also argue that since Cruise et al teach hydrogels, that it is not germane to the instant invention. This one teaching does not negate the other teachings in Cruise et al as noted prior in the record and further, all other contentions with regard to Cruise et al and its teachings are but allegations that lack factual support. As a result, they are assigned no patentable weight.
Applicants also argue that there is no support to combine the teachings of Phan et al with the teachings of Pinchuk, because Pinchuk does not teach or suggest the use of any radiation treatment. By Applicants' own admission, however, Pinchuk does disclose the release of therapeutic agents over time. Given the state of the art, particularly the release of therapeutic agents over time in stent systems, and as well, the reasons made previously of record for combining the references, the Applicants' assertion that there is not support to modify the teachings of Phan et al with the teachings of Pinchuk is but an allegation lacking factual support.
With regard to the Furst reference, Applicants also argue that support for its use cannot be sustained, most notably because the amount of radiation used in Furst is less than 2000 rads. The Furst reference is not utilized as a single reference to anticipate the instant invention. Rather, it is used in concert with, to modify other references that teach stent technology. It would not be unreasonable or outside the motivation of one of ordinary skill in the art to modify Furst et al by the teachings in the other cited references to arrive at the radiation dosage taught by the instant invention. .